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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/033,400	12/27/2001	Peng-Sheng Chen	18810-81904	9919

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SIDLEY AUSTIN BROWN & WOOD
555 West Fifth Street
Los Angeles, CA 90013

EXAMINER

PARAS JR, PETER

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/033,400		CHEN, PENG-SHENG	
	Examiner		Art Unit	
	Peter Paras, Jr.		1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment received on 12/4/03 has been entered. Claims 1 and 6-9 have been amended. Claim 10 has been cancelled. New claims 11-21 have been added. Claims 1-9 and 11-21 are pending and are under current consideration.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-9 and 11-21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The previous rejection is maintained for the reasons of record advanced on page 2 of the Office action mailed on 8/26/03.

Applicant's arguments filed on 12/4/03 have been fully considered but they are not persuasive. Applicants have amended the claims to the extent that the animal model system comprises a canine test subject. Applicants submit the newly presented claim amendments overcome the instant rejection. See page 7 of the amendment.

In response, the Examiner maintains the scope of the claims still embraces humans. The claims are directed to an *animal model system comprising* a canine test subject. The open language of the claims embraces not only canines but also other animals including humans. In other words the term "comprises" does not limit the claims to only canines. Given the open language of the claims a reasonable interpretation of such would include other animals as well. Thus, it is maintained a

Art Unit: 1632

human being is non-statutory subject matter. As such, the recitation of the limitation "non-human" would be remedial for the claims. See 1077 O.G. 24, April 21, 1987.

Accordingly, the previous rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 and 11-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The previous rejection is maintained for the reasons of record advanced on pages 2-4 of the Office action mailed on 8/26/03.

Applicant's arguments filed on 12/4/03 have been fully considered but they are not persuasive. Applicants have amended the claims to the extent that the animal model system comprises a canine test subject. Applicants submit the newly presented claim amendments overcome the instant rejection. See page 8 of the amendment.

In response, the Examiner maintains the scope of the claims still embraces animals other canines. The claims are directed to an *animal test system comprising a* canine test subject. The open language of the claims embraces not only canines but

other animals as well. In other words the term "comprises" does not limit the claims to only canines. Given the open language of the claims a reasonable interpretation of such would include other animals as well.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The previous rejection is maintained for the reasons of record advanced on pages 5-6 of the Office action mailed on 8/26/03.

Applicant's arguments filed 12/4/03 have been fully considered but they are not persuasive. Applicants argue the term neurotrophic vector embraces neurotrophic chemicals, substances, or hormones. Applicants further argue the skilled artisan would have been aware of other neurotrophic vectors as well as their structural and functional relationships. Applicants refer to neurotrophins, of which nerve growth factor (NGF) is a species, as examples of neurotrophic vectors. Applicants submit species of neurotrophins are conventional in the art. See pages 8-10 of the amendment.

In response, the Examiner maintains the specification has described NGF but has not described neurotrophic vectors. NGF is a growth factor that is a neurotrophin. However, a neurotrophic vector is correctly interpreted to embrace a DNA sequence that is a vehicle for transferring a gene. A neurotrophic vector could comprise a gene encoding a neurotrophin, such as NGF. It is maintained, based on such an

interpretation, the specification has not provided a description for neurotrophic vectors as embraced by the claims. It is further maintained there is no evidence of record of a relationship between the structures of any neurotrophic vectors and nerve growth factor that would provide any reliable information about the structure of the neurotrophic vectors within the genus. Finally, it is maintained there is no evidence of record that nerve growth factor had a known structural relationship to neurotrophic vectors; the specification discloses only nerve growth factor for use in the claimed invention.

Accordingly, the rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-7, 13-14, and 18-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The previous rejection of claims 6-7 is maintained for the reasons of record advanced on page 7 of the Office action mailed on 8/26/03.

Applicant's arguments filed 12/4/03 have been fully considered but they are not persuasive. Applicants submit the instant specification provides guidance as to relevant ICD therapies for prevention and treatment of cardiac arrhythmias. See pages 10-11 of the amendment.

In response, the Examiner maintains the claims are indefinite as written. It is maintained the specification has not defined techniques applied by an ICD. As such it is not known what is meant by techniques applied by an ICD. Applicants have argued that ICD therapies have been exemplified by the instant specification. However, it appears that ICD therapies are not the same as techniques applied by an ICD. The specification has discussed that an ICD can provide cardioversion or defibrillation pulses as a therapy but remains unclear as to what is a "technique" applied by an ICD.

Accordingly, the previous rejection is maintained for the reasons of record.

The following are new grounds of rejection necessitated by the addition of the new claims:

Claims 13-14 and 18-19 are indefinite as written. The claims embrace an ICD that further applies techniques to prevent the occurrence of further arrhythmias. The claim is unclear because neither the specification nor the art of record define techniques applied by an ICD. As such it is not known what is meant by techniques that are applied by an ICD. Clarification is required.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

Art Unit: 1632

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is (571) 272-0732. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Official Fax Center number is (703) 872-9306.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (571) 272-0532.

Peter Paras, Jr.
Art Unit 1632

PETER PARAS, JR.
PRIMARY EXAMINER

A handwritten signature in black ink that reads "Pete Paras Jr." in a cursive, stylized font.